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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)		
	09/974,757	HENDERSON ET AL.		
Office Action Summary	Examiner	Art Unit		
	Leon Y Lum	1641		
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status				
1) Responsive to communication(s) filed on <u>02 Ja</u> 2a) This action is FINAL . 2b) This 3) Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro			
Disposition of Claims				
4) ☐ Claim(s) 10-26 and 28-33 is/are pending in the 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 10-26 and 28-33 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	vn from consideration.			
Application Papers				
9) The specification is objected to by the Examine 10) The drawing(s) filed on 09 October 2001 is/are: Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Ex	accepted or b) \square objected drawing(s) be held in abeyance. Section is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document * See the attached detailed Office action for a list 	s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage		
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:			

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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed on September 19, 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the foreign patent documents and non-patent literature have not been provided. It has been placed in the application file, but the information referred to therein, with the exception of US patents and US pre-grant publications, has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

2. Claims 18-19 and 21-25 are objected to because of the following informalities:

The claims recite binding affinities relating to a plurality of interaction types between an object and a material that are not disclosed in the specification or the indicated patent that has been incorporated by reference. Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 18-19 and 21-25 recite, in line 1 of the claims, protein, nucleic acid, receptor/ligand, cell/cell, cell/substrate, virus/virus, and virus substrate interactions, respectively. Applicant is advised to include in the specifications teaching of the said interactions.

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 10-26 and 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. Claim 10 recites the limitations "the object" and "the corresponding material" in line 8 of the claim. There is insufficient antecedent basis for this limitation in the claim. It is unclear whether the object and the corresponding material refer to the "at least one object" and "one or more materials" recited in line 5 of the claim, or to an object and material that is not mentioned.

Claim 13 recites the limitation "wherein scanning the surface" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the corresponding material" in line 2 of the claim.

There is insufficient antecedent basis for this limitation in the claim. It is unclear whether the corresponding material refers to the "one or more materials" recited in line 1 of claim 10, or to a material that is not mentioned.

Claim 26 recites the limitation "the interaction force" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 28 recites the limitation "the binding affinity" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 30-32 recites the limitation "the objects" in line 1 of the claims. There is insufficient antecedent basis for this limitation in the claim. The term "the objects" requires a plurality that is not necessarily required in the parent claim 28, which recites "at least one object", and may comprise only one object.

Claim 33 recites the limitation "the interaction force" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

6. In claim 26, line 11, the phrase "collecting at least one object still affixed to the surface" is confusing and indefinite. Does the collection refer an object that is still affixed to the surface after having the greater second force applied to it, or an object that remained after having the first force applied to it? Please clarify and distinguish between objects that have either the first, second, or both forces applied to it.

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7. Claims 10 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the calculation of binding affinity from the force measurements. The specifications do not disclose the steps required to translate force values into binding affinity or what units determine a binding affinity. It is also not clear whether the force is directly used in the calculation or what equations, if necessary, are used.

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- 8. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to obtain the "interaction force between an object and a surface" stated in line 1 of the claim from the limitations of depositing at least one material on a surface, affixing at least one object to the material, scanning the surface with an atomic force microscope, applying a force to at least one object with the atomic force microscope, removing objects from the surface by this force, scanning the surface to locate at least one object that is still affixed to the surface, applying a second greater force to the at least one object on the surface, and collecting at least one object still affixed to the surface.
- 9. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how to determine the "binding"

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affinity between an object and a material deposited on a surface" stated in lines 1-2 of the claim from the limitations of depositing at least one material on a surface, binding at least one object to at least one material, applying a first force to the at least one object with an atomic force microscope, collecting at least one object that has been removed from the surface by the first force, applying a second force to the at least one object on the surface using the atomic force microscope to remove at least one object from the surface, collecting at least one object that has been removed from the surface by the

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

second force, and repeating the above steps.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 10-12, 14, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mazzola et al (Imaging Biomolecule Arrays by Atomic Force Microscopy, Biophysical Journal, 68 (1995) 1653-1660).

Mazzola et al anticipate the instant claim by teaching a method to determine a binding affinity between an object and material comprising obtaining a surface with a

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material (biotin; page 1654, Figure 1 and caption, lines 1-10), affixing an object (streptavidin; page 1654, Figure 1 and caption, lines 1-10) to the material, applying a force to the object to remove the object (scans at the highest force; page 1657, column 1, lines 6-14 and column 2), and calculating a binding affinity between the object and material from the force (force required for mechanical dissociation should reflect to the free energy or enthalpy of a single molecular interaction; page 1659, column 2, lines 10-21).

Regarding claim 11, Mazzola et al teach that the force is monitored (repeated scans at the highest possible force; page 1657, column 1, lines 13-14).

Regarding claim 12, Mazzola et al teach that a scanning probe microscope is scanned over the surface (page 1658, Figure 5 caption, line 1).

Regarding claim 14, Mazzola et al teach that a removed object is collected (dislodged protein was adsorbed to the scanning tip; page 1657, column 2, lines 4-5)

Regarding claim 21, Mazzola et al teach that the binding affinity interaction involves receptor/ligand interactions (page 1654, Figure 1 and caption, lines 1-10).

12. Claims 10-12, 17-18, and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al (USP 5,874,668).

Xu et al anticipate the instant claims by teaching a method to determine a binding affinity between an object and material comprising obtaining a surface with an immobilized material (receptor, antibody, etc.; numeral 38 in Figure 3D), affixing an object to the material (antibody, ligand or other protein or chemical attached to a

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bioprobe tip and contacted with a molecule or subunit of a molecule; column 7, lines 38-40 and 55-60), applying a force to object to remove the object (strong force needed to separate object on bioprobe tip and molecule; column 7, lines 57-60), and calculating a binding affinity between the object and material from the applied force (measure the force required to separate the bioprobe tip from the specimen which estimates the force of the binding between molecular pairs; column 7, lines 65-67 and column 8, lines 1-2).

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Regarding claim 11, Xu et al teach that the force is monitored (force is measured while scanning with the AFM; column 7, lines 60-62).

Regarding claim 12, Xu et al teach that the surface is scanned with a scanning probe microscope (the scanning probe tip of an AFM scans the surface; column 6, lines 52-53 and 61-62).

Regarding claims 17-18 and 22-25, Xu et al teach that the binding affinity interactions are molecular interactions (column 8, lines 1-2), involve protein interactions (column 17, lines 38-40), involve cell-cell interactions (column 7, lines 31-33 and column 8, line 62), involve virus/virus interactions (column 7, lines 38-40 and column 8, line 62) and involve cell/substrate and virus/substrate interactions (column 8, lines 59-62).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 14. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 16. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzola et al (Imaging Biomolecule Arrays by Atomic Force Microscopy, Biophysical Journal, 68 (1995) 1653-1660) in view of Green et al (USP 5,992,226).

Mazzola et al reference has been disclosed above, but fails to teach the method of applying a force to an object in a liquid medium.

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Green et al teach a method of measuring an applied force between two compounds in any medium or environmental condition used in atomic force microscopy, including under a liquid medium in which experimental conditions such as pH and ionic concentration can be controlled and varied (column 13, lines 22-35).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the method of Mazzola et al, a method of applying a force to an object in a liquid medium, as taught by Green et al, in order to determine the affinity of bound objects under varying experimental conditions.

17. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzola et al (Imaging Biomolecule Arrays by Atomic Force Microscopy, Biophysical Journal, 68 (1995) 1653-1660) in view of Baselt et al (A biosensor based on magnetoresistance technology, Biosensors & Bioelectronics, 13 (1998) 731-739).

Mazzola et al reference has been disclosed above, but fails to teach the methods of applying incrementally increasing forces to an object.

Baselt et al teach a method of applying incrementally increasing forces to an object to obtain the rupture force (page 732, lines 13-15). Specifically, Baselt et al state "When this force reached – 600 pN, the DNA-DNA bond at either the tip or substrate broke, therefore eliminating the force on the cantilever." This teaching implies that the force required to break the interactions forces is not known, and an incremental rise in force is applied in order to obtain the required force.

Therefore, one of ordinary skill in the art at the time of the invention would include in the method of Mazzola et al, the method of applying incrementally increasing forces to an object, as taught by Baselt et al, in order to reach the force sufficient to remove an object since it may not be known what amount of force is required.

18. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzola et al (Imaging Biomolecule Arrays by Atomic Force Microscopy, Biophysical Journal, 68 (1995) 1653-1660) in view of Baselt et al (A biosensor based on magnetoresistance technology, Biosensors & Bioelectronics, 13 (1998) 731-739), as applied to claim 15 above, and in further view of Xu et al (USP 5,874,668).

Mazzola et al and Baselt et al references have been disclosed above, but fail to teach the collection of objects remaining on the surface.

Xu et al teach that objects still attached to the surface can be collected (removed by washing the bioprobe tip and test chamber with organic solvents; column 7, lines 51-53) so that the surfaces can be cleaned and reused for future testing.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the methods of Mazzola et al and Baselt et al, the method of collecting objects from the surface, as taught by Xu et al, in order to clean the surface for future object immobilizations and testing purposes.

19. Claims 17-18 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzola et al (Imaging Biomolecule Arrays by Atomic Force

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Microscopy, Biophysical Journal, 68 (1995) 1653-1660) in view of Xu et al (USP 5,874,668).

Mazzola et al reference has been disclosed above, but fail to teach that the binding interactions involve molecular, protein, cell/cell, cell/substrate, virus/virus, and virus/substrate interactions.

Xu et al teach that the binding affinity interactions between an object and material can be molecular interactions (column 8, lines 1-2), involve protein interactions (column 17, lines 38-40), involve cell-cell interactions (column 7, lines 31-33 and column 8, line 62), involve virus/virus interactions (column 7, lines 38-40 and column 8, line 62) and involve cell/substrate and virus/substrate interactions (column 8, lines 59-62) and can be detected by atomic force microscopy to determine interactions between alternative objects and materials.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Mazzola et al, the method of applying binding interactions between molecular, protein, cell/cell, cell/substrate, virus/virus, and virus/substrate interactions, as taught by Xu et al, in order to determine interactions between alternative objects and materials using atomic force microscopy.

20. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzola et al (Imaging Biomolecule Arrays by Atomic Force Microscopy, Biophysical Journal, 68 (1995) 1653-1660) in view of Green et al (USP 5,992,226).

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Mazzola et al reference has been disclosed above, but fails to teach the method of having binding affinities that involve nucleic acid or antibody/antigen.

Green et al teach a method of having nucleic acid (DNA or RNA) or antibody/antigen interactions to screen for different types of reactions simultaneously without having to change the sample surface (column 12, lines 35-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the method of Mazzola et al, a method of having nucleic acid or antibody/antigen interactions, as taught by Green et al, in order to simultaneously screen for numerous types of interactions without having to change the sample surface.

21. Claims 26 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzola et al (Imaging Biomolecule Arrays by Atomic Force Microscopy, Biophysical Journal, 68 (1995) 1653-1660) in view of Baselt et al (A biosensor based on magnetoresistance technology, Biosensors & Bioelectronics, 13 (1998) 731-739) and Xu et al (USP 5,874,668).

Mazzola et al teach a method of depositing a material on a surface (biotin on a substrate; page 1654, Figure 1 and caption, lines 1-10), affixing an object (streptavidin; page 1654, Figure 1 and caption, lines 1-10) to a material, scanning the surface with an atomic force microscope to locate the objects (contact scans at the highest tip force), applying a force to the object with an atomic force microscope, determining the force

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applied, removing and collecting the object from the surface (dislodged protein was adsorbed to the scanning tip) (page 1657, column 1, lines 6-14 and column 2, lines 1-6).

In regards to claim 26, Mazzola et al teach a method of scanning the surface to locate objects still attached to the surface, and repeating the process of applying (page 1657, column 1, lines 6-14 and column 2, lines 1-6).

In regards to claim 28, Mazzola et al teach a method of repeating the process of applying a force and removing the object(repeated scans) (page 1657, column 1, lines 6-14 and column 2, lines 1-6).

In regards to claim 29, Mazzola et al teach that a binding affinity between an object and a material can be calculated using the force applied (page 1659, column 2, lines 10-21).

Mazzola et al fail to teach the methods of applying a second greater force to objects using an atomic force microscope, applying a 1st and 2nd force to the object, and collecting objects still attached to the surface.

Baselt et al teach a method of applying multiple forces to an object (page 732, lines 13-15). Specifically, Baselt et al state "When this force reached – 600 pN, the DNA-DNA bond at either the tip or substrate broke, therefore eliminating the force on the cantilever." This teaching implies an incremental rise in force, which is inherently a combination of multiple distinct forces, and is applied for the purpose of removing objects that may require different amounts of force.

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Xu et al teach that objects still attached to the surface can be collected (removed by washing the bioprobe tip and test chamber with organic solvents; column 7, lines 51-53) so that the surfaces can be reused for future testing.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the method of Mazzola et al, the method of applying a second greater force or distinct 1st and 2nd forces to objects using an atomic force microscope, as taught by Baselt et al, in order to remove objects from the substrate that may be bound with different interaction forces.

In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the method of Mazzola et al, the method of collecting objects from the surface, as taught by Xu et al, in order to clean the surface for future object immobilizations and testing purposes.

- 22. Claims 30-31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzola et al (Imaging Biomolecule Arrays by Atomic Force Microscopy, Biophysical Journal, 68 (1995) 1653-1660) in view of Baselt et al (A biosensor based on magnetoresistance technology, Biosensors & Bioelectronics, 13 (1998) 731-739), as applied to claim 28 above, and in further view of Henderson et al (USP 5,763,768).
- 23. Mazzola et al and Baselt et al references are disclosed above. In addition,
 Baselt et al teach that the interaction force between an object and material can be an
 antibody/antigen interaction (page 731, Introduction, line 2), but both references fail to

teach that objects can be deposited using non-specific binding and covalent binding interactions.

Henderson et al teach that interactions between the object and a material (modified tips and surfaces) can be non-specific (column 9, lines 63-65 and column 10, lines 2-4), that interactions between the object and a material (microparticles on tips and molecular species) can be covalent (column 4, lines 30-33), and are two alternative methods for binding an object to a material.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the methods of Mazzola et al and Baselt et al, the method of applying non-specific and covalent interactions between objects and materials, as taught by Henderson et al, in order to use alternative methods for binding an object with a material.

- 24. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazzola et al (Imaging Biomolecule Arrays by Atomic Force Microscopy, Biophysical Journal, 68 (1995) 1653-1660) in view of Baselt et al (A biosensor based on magnetoresistance technology, Biosensors & Bioelectronics, 13 (1998) 731-739), as applied to claim 28 above, and in further view of Green et al (USP 5,992,226) Xu et al (USP 5,874,668).
- 25. Mazzola et al and Baselt et al references are disclosed above, but fail to teach that objects can be proteins, nucleic acids, antibodies, cells, or viruses.

Xu et al teach a method of having objects selected from proteins (column 17, lines 38-40), cells (column 7, lines 31-33 and column 8, line 62), and viruses (column 7,

lines 38-40 and column 8, line 62) to screen for different types of reactions among alternative objects.

Green et al teach a method of having objects selected from nucleic acids (DNA or RNA) or antibodies to screen for different types of reactions simultaneously without having to change the sample surface (column 12, lines 35-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the methods of Mazzola et al and Baselt et al, the methods of having objects selected from proteins, nucleic acids, antibodies, cells, or viruses, as taught by Green et al and Xu et al, in order to screen for different types of reactions among alternative objects simultaneously without having to change the sample surface.

Conclusion

- 26. The prior art made of record and not relied upon are considered pertinent to applicant's disclosure.
- 27. Allen et al (Detection of Antigen-Antibody Binding Events with the Atomic Force Microscope, Biochemistry, 1997, 36, 7457-7463) teach a method determining the interactions between antibodies and antigens using an atomic force microscope, including unbinding of an antibody-antigen complex.

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28. Colton et al (USP 5,372,930) teach chemically modifying a substrate and tip with antigens, antibodies, nucleic acids, or chelating agents, and measuring the forces between substrate and tip with an atomic force microscope.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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LONG V. LE SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

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